Within each SuperGroup, the Examiner further restricted the claims to each particular open reading frame (ORF);

In response to this restriction requirement, Applicants provisionally elect SuperGroup A, 1-21, 23, 40-45, 65-66, 68-69, and 71-73, Group 1 relating to ORF 8, with traverse.

The Restriction Between the SuperGroups is Unnecessary.

Applicants submit that restriction between SuperGroups A through E is unnecessary. According to MPEP §803, the Examiner should examine all claims in an application, **even though they are directed to distinct inventions**, unless to do so would create a **serious burden**. In the instant case, the claims of SuperGroups A through E all pertain to various bleomycin (BLM) open reading frames, polypeptide, and uses thereof. A search for prior art pertaining to bleomycin nucleic acid sequences and/or polypeptides, is expected to identify prior art, if it exists, relevant to any or all of the claims encompassed by the identified SuperGroups.. Thus, a search for art relevant to SuperGroups A through E together, entails no greater burden than a search for art relevant to SuperGroup A alone. Accordingly, Examination of SuperGroups A through E together entails no serious burden and the restriction between these SuperGroups should be withdrawn.

The Restriction Between the Open Reading Frames (ORFs) is Legally Improper.

The restriction between the various ORFs comprising each SuperGroup is legally improper. Rather, the Examiner should have imposed and election of species.

In making such a restriction, the Examiner effectively requires that a single claim (*e.g.*, claim 1) be divided up and presented in several applications (*i.e.* the Examiner effectively requests that claim 1 be divided up and presented in 34 different applications). This flatly contravenes accepted law. As stated by the CCPA:

> As a general proposition, an applicant has a right to have ***each claim*** examined on the merits.
>
> * * *

> If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.
>
> * * *
>
> §121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions, ... It does not provide a basis under the authority of the Commissioner to *reject* a particular *claim* on that same basis.
>
> * * *
>
> We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses. *In Re Weber, Soder and Boksay* 198 USPQ 328, 331-332 (CCPA 1978)

See also, *In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) and *In Re Haas* 198 USPQ 334-337 (*In Re* Haas *II*).

The CCPA thus recognized that an Examiner **may not** reject a particular claim on the basis that it represents "independent and distinct" inventions. *See, In re Weber Soder and Boksay, supra.* Moreover, **the CCPA recognized that imposition of a restriction requirement on a single claim is just such an improper rejection.**

In particular, the courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I, and In Re Haas II.* More specifically, the CCPA expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- **no matter how broad, which means no matter how many independently**

patentable inventions may fall within it. [emphasis added] *In Re Weber* at 334.

Applicants recognize that instead of improperly imposing a restriction requirement on a single claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim. *See*, 37 C.F.R. §1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §112 are complied with. *See, e.g.,* the MPEP at 803.02, *In Re Wolfrum* 179 USPQ 620 (CCPA, 1973) and *In re Kuehl* 177 USPQ 250 (CCPA, 1973).

Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications that are incapable of capturing the intended scope of the application. It should be clear that the added cost of filing and prosecuting 170 divisional patent applications in the present case does not strike an appropriate balance between the administrative concerns of the office and Applicants statutory rights as inventors.

Finally, Applicants note that the CCPA has explicitly held that improper restriction of a single claim is a decision under the jurisdiction of the Board of Appeals, and the Federal Courts. This is in contrast to simple administrative decisions regarding ordinary restriction requirements, which are not generally subject to Appellate review. *See, In Re Haas I, supra.* Because restriction of a single claim into multiple groups is tantamount to a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the Board of Appeals and the courts have jurisdiction over the decision. Accordingly, **Applicants expressly reserve the right to appeal any decision that may be made regarding the present response to the Patent Office Board of Appeals and to the Federal Circuit**.

The Restriction Between the Open Readign Frames (ORFs) Improperly Contravenes M.P.E.P. §803.04.

The restriction between the ORFs within each SuperGroup improperly contravenes M.P.E.P. §803.04. The various ORFs recited within each SuperGroup are BLM gene cluster open reading frames. MPEP §803.04 expressly states that

> [T]o further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on *the* Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucletoide Squences* 1192 O.G. 68 (November 19, 1996)
>
> **It has been determined that normally ten sequences constitute a reasonable number o for examination pruposes.** [emphasis added] (MPEP §803.04)

The language of this section **is not** limited to Expressed Sequence Tags (ESTs). The language simply goes to "nucleotide sequences." **Thus, within each SuperGroup, Applicants should be entitled to have at least 10 open reading frames (ORFs) examined together.**

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-7871.

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